

**Remarks**

Applicant, herein, has amended claim 19; has canceled claims 1-11 and 15-18; and has added new claims 23-26. Six (6) claims remain pending in the application, claims 19, 20 and 23-26, of which claim 19 is independent. Applicant respectfully requests reconsideration of the pending claims, in view of the claim amendments above and comments below.

***Election/Restriction***

The Examiner stated that claims 4, 12-14 and 20-22 were withdrawn as non-elected. However, in the response to restriction requirement mailed by applicant on September 30, 2003 (paper number 7), claims 1-11 and 15-20 were elected. Thus, both claim 4 and claim 20 were elected. Further, as both claim 4 and claim 20 were rejected in the present Office action, applicant assumes these claims were not intentionally withdrawn by the Examiner.

***Specification***

The Examiner objected to the specification as failing to provide proper antecedent basis for the claimed subject matter, pursuant to 37 CFR 1.75(d)(1) and MPEP 608.01(o).

Specifically, the Examiner stated: "[t]he data receiving circuit functional limitations are not supported [by] the specification. It is unclear what parameters are used by the control circuit to control the operation of the driver."

Claim 1 included "the data receiving circuit" and claims 2-18 depended, directly or indirectly on claim 1. By way of the present amendment, applicant has canceled claims 1-11 and 15-18, and claims 12-14 were earlier withdrawn as non-elected. As a result, this objection for failure to provide antecedent bases for claimed subject matter is now moot, in light of these claim cancellations.

***Claim Rejections - 35 USC § 112***

Claims 1-11 and 15-18 were rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement as "the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Specifically, the rejection states that the specification "fails to teach what control parameters are used by the control circuit to control the operation of the driver."

Claim 1 included "the control circuit" and claims 2-18 depended, directly or indirectly on claim 1. By way of the present amendment, applicant has canceled claims 1-11 and 15-18, and claims 12-14 were earlier withdrawn as non-elected. As a result, this rejection for failure to comply with the written description requirement is now moot, in light of these claim cancellations.

***Claim Rejections - 35 USC § 102***

Claims 1, 3, 5-7, 15 and 19-20 were rejected under 35 U.S.C. 102(b) as anticipated by Reinicke (U.S. Patent No. 4,482,346). As discussed above, claims 1-11 and 15-18 have been canceled by way of the present amendment, so this rejection is now moot relative to claims 1, 3, 5-7 and 15. In view of the remarks presented hereafter, such alleged anticipation of claims 19 and 20 is respectfully traversed.

The rejection states that:

Reinicke discloses an implantable microminiature infusion pump comprising a reservoir 12, a driver/pump, an exit portal 16, a control circuit and data receiving circuit 22. The reservoir has a septum 34, the device includes at least one regulator 18, and a power source 24. The pump being [sic] a diaphragmatic type pump.

MPEP 2131 states:

To anticipate a claim, the reference must teach every element of the claim.

Applicant respectfully submits that Reinicke does not show a means "for delivering therapeutic electrical stimulation to the patient" (see claim 19) or a "sensor for sensing a need for or therapeutic effect of the therapeutic substance and electrical stimulation" (see claim 20). As such, this rejection is overcome.

Claims 1, 3, 5-9, 11 and 18-20 were rejected under 35 U.S.C. 102(b) as anticipated by Harpstead et al (U.S. Patent No. 5,497,951). As discussed above, claims 1-11 and 15-18 have been canceled by way of the present amendment, so this rejection is now moot relative to claims 1, 3, 5-9, 11 and 18. In view of the amendment to claim 1 above, the applicants believe this rejection is overcome, as discussed further below. And, in view of the remarks presented hereafter, such alleged anticipation of claim 20 is respectfully traversed.

While not necessarily agreeing with the rejection of claim 19 as anticipated by Harpstead et al, the applicants have herein amended claim 19 to further clarify the invention and to further distinguish the invention from the device of Harpstead et al. Only certain portions of the Harpstead et al device are implanted. See, for instance, Figure 1. Reference number 12 represents the skin of the patient 10. Column 2, lines 63-66 state:

A conventional neurostimulator 18 is used to generate data and an electrical power signal suitable for producing stimulation pulses by transmitting radio frequency electrical energy from an antenna 20.

After amendment, claim 1 includes "means integral with the therapeutic substance delivering means and implanted in the patient for delivering therapeutic electrical stimulation to the patient". As the means for delivering electrical stimulation disclosed by Harpstead et al. is clearly external to the patient, the rejection of claim 19 as anticipated by Harpstead et al has been overcome.

As stated earlier, the alleged anticipation of claim 20 by Harpstead et al. is respectfully traversed. The subject rejection states that:

Harsptead [sic] et al. disclose an implantable infusion pump with a reservoir 84, a driver, an exit port 70, 170, electrodes 150-153, control circuit and data receiving circuit/antenna 90, septum 70.

MPEP 2131 further states:

"The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The applicants respectfully submit that Harpstead et al do not show a "sensor for sensing a need for or therapeutic effect of the therapeutic substance and electrical stimulation" as recited in claim 20. As such, the rejection of claim 20 as anticipated by Harpstead et al is overcome. This rejection is further overcome by way of the present amendment for the same reasons given above in support of currently amended claim 19, upon which claim 20 depends.

### ***Claim Rejections - 35 USC § 103***

Claims 16-18 were rejected under 35 U.S.C. 103(a) as unpatentable (obvious) over Reinicke (U.S. Patent No. 4,482,346). As discussed above, claims 16-18 have been canceled by way of the present amendment, so this rejection is now moot.

### ***New Claims***

New claims 23-26 are presented herein. Claims 23 and 24 depend from claims 19 and 20, respectively, and "further includ[e] means within the implantable microminiature infusion pump for providing power" to the device. Support for claims 23 and 24 is found throughout the application, including in originally filed claims 7 and 9 and in paragraphs [0047] – [0050]. New claims 23 and 24 should be allowable for the same reasons given above in support of claims 19 and 20, upon which claims 23 and 24 depend.

Claims 25 and 26 depend from claims 19 and 20, respectively, and "further includ[e] at least one lead attached to the implantable microminiature infusion pump...." Support for claims 25 and 26 is found, for instance, in the subject specification at paragraph number [0040]. New claims 25 and 26 should be allowable for the same reasons given above in support of claims 19 and 20, upon which claims 25 and 26 depend.

After entry of this amendment, all pending claims depend directly or indirectly from independent claim 19. As such, applicants respectfully request consideration of independent claim 19, and its dependent claims, in light of these remarks and the related claim amendments.

In view of the foregoing remarks and amendments, it is respectfully submitted that the rejections have been overcome and that the previously-rejected pending claims and the newly-submitted claims are in condition for allowance. An indication of allowability of all pending claims, claims 19, 20 and 23-26, is earnestly solicited.

Respectfully Submitted,

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Date

Laura H. Bishop  
Laura Haburay Bishop  
Reg. No. 47,424

Please direct all written inquiries to:  
Bryant R. Gold  
Advanced Bionics Corporation  
12740 San Fernando Road  
Sylmar, CA 91342

Please direct all telephone inquiries to:  
Laura Haburay Bishop  
Telephone: (661) 362-1906  
Fax: (661) 362-1507